

# IQ

## for ALEXYS LC-ECD systems

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# Table of contents

Table of contents .....	1
Introduction .....	2
<b>Chapter 1 .....</b>	<b>1</b>
Identification .....	1
<b>Chapter 2 .....</b>	<b>2</b>
Preparations .....	3
<b>Chapter 3 .....</b>	<b>3</b>
Unpacking.....	4
<b>Chapter 4 .....</b>	<b>4</b>
Installation.....	5
<b>Chapter 5 .....</b>	<b>5</b>
Operational familiarization .....	6
<b>Chapter 6 .....</b>	<b>6</b>
Maintenance instructions.....	7
<b>Chapter 7 .....</b>	<b>7</b>
Troubleshooting instructions.....	8
<b>Chapter 8 .....</b>	<b>8</b>
IQ certification.....	9
<b>Chapter 9 .....</b>	<b>10</b>
Non-conformance record.....	10
Comments .....	10
<b>Appendix I.....</b>	<b>11</b>
ALEXYS Operator Checklist.....	11

# Introduction

This document describes the installation procedure as advised by the manufacturer. It is a result from our interpretation of many regulations and laboratory practices. In addition, feedback from users and representatives helped us to finalize this procedure.

All qualification checks have to be approved, or should be marked "n/a" if not applicable. Any deviation observed must be documented in the 'non-conformance' record. All relevant documents regarding system delivery and installation qualification must be filed together in one location.

As regulations and customer requirements may change, the manufacturer reserves the right to introduce changes without prior notice. For details on functionality, operation and theory, reference is made to the instruments user manuals.

C H A P T E R 1

# Identification

## Engineer

The undersigned engineer certifies that he/she is trained and qualified to perform an Installation Qualification on the ALEXYS® LC-EC System.

Company: .....

Performer: .....  
Name Initials

Position: .....

Signature: .....  
(Antec representative trained and qualified to perform PQ procedures)

## Reviewer/customer

The undersigned reviewer/customer accepts that the above-mentioned engineer is trained and qualified to perform a Installation Qualification on the ALEXYS LC-EC System.

Company: .....

Department: .....

Reviewer/  
Customer: .....  
Name Initials

Position: .....

Signature: .....  
(Owner-designated authorized person)

## ALEXYS instruments

DECADE Elite	p/n:	.....	s/n:	.....
Flow cell 1	p/n:	.....	s/n:	.....
	Working electrode type:	.....		
	Reference electrode type:	.....		
Flow cell 2*	p/n:	.....	s/n:	.....
	Working electrode type:	.....		
	Reference electrode type:	.....		
P6.1 L pump 1	p/n:	.....	s/n:	.....
P6.1 L pump 2*	p/n:	.....	s/n:	.....
AS110 / electrical injector	p/n:	.....	s/n:	.....
	Nr of ports on valve:	.....		
	Size of ports on valve:	.....		
Clarity software (key)	p/n:	.....	s/n:	.....
	Clarity software version:	.....		
	Clarity dongle user code			

\*s/n: fill in n/a if only 1 unit is installed.

Manufacturer Antec Scientific

Supplier .....

Date of delivery .....

Warranty until .....

Verified by (customer): .....

Deviations (Y/N): .....

Comments:

## CHAPTER 2

**Preparations**

For a successful installation a few **preparations** must be made. Note that part of this is also a responsibility of the user. Relevant issues are explained in detail in the "Installation Guide" sections of the user manuals and for some applications there is a Requirements document that can be sent to the customer in advance of installation to prepare correctly.

1. The installation site should meet the environmental specifications as described in the ALEXYS users manuals.
2. The chemicals (and water) used for preparation of mobile phase must be of specific grade (or better). Any trace of impurity will lead to elevated background current and an increase of noise.
3. Operating supplies and consumables should be available.
4. In a multi-purpose lab (that is not ECD-only) precautions should be taken to avoid contamination of high purity chemicals. We advise to keep a separate set of buffer salts, standards, glass ware and other small supplies for ECD only.

**Table I**

<b>Check</b>	<b>In conf.</b>	<b>Non conf. ref. *</b>
Section "installation guide" and "safety practices" in user manual(s) is noticed	○	
Environmental conditions are in accordance to recommendations in manual	○	
Purity of all mobile phase chemicals is HPLC grade or better	○	
The water used for preparation of mobile phase has a resistivity > 18 MOhm.cm and TOC<10ppb	○	

\* Any deviation observed must be documented in the 'non-conformance' record.

Verified by (customer): .....

Deviations (Y/N): .....

Comments:

## CHAPTER 3

# Unpacking

- Before opening, inspect the transport boxes for external damage. In case of damage, immediately inform the transport company, otherwise she may not accept any responsibility. Keep the transport boxes as it is designed for optimum protection during transport and it may be needed again.
- Carefully unpack the system and inspect it for completeness and for possible damage. Contact the supplier in case of damage or if not all marked items on the checklist(s) are included.
- Prior to shipment, the system was inspected and tested to ensure the best possible performance. The results of all tests are included.

**Table II**

Check	In conf.	Non conf. ref. *
Delivery is in accordance with order	○	
Delivery is undamaged	○	
All items on checklist(s) are included	○	
Certificates of performance are included		
- P6.1L pump	○	
- AS 110 autosampler	○	
- DECADE Elite detector	○	
- Flow cell(s)	○	
- Column(s)	○	
User manuals are included (USB stick)	○	

\* Any deviation observed must be documented in the 'non-conformance' record.

Verified by (customer): .....

Deviations (Y/N): .....

Comments:



## CHAPTER 4

**Installation**

The **installation** procedure of the different instruments and parts of the system is described in the users manuals (Chpt. "Installation Guide").

Some points to highlight:

1. The system hardware must be passivated as part of the installation
2. The column and mobile phase must be electrochemically clean.
3. Flush the (new)column according to the manufacturers recommendations before running mobile phase through.
4. In case that the mobile phase contains ion-pairing agent, stabilize a new unused C18 column overnight with running mobile phase before attaching the flow cell.
5. If a flow cell with ISAAC™ type reference electrode is used, the ISAAC requires a fixed concentration (2 or 8 mmol/L) chloride ions (KCl or NaCl) in the mobile phase.

**Table III**

<b>Check</b>	<b>In conf.</b>	<b>Non conf. ref. *</b>
Installation procedure is done in accordance to user's manuals.	○	
System passivated in accordance to recommendations in manual	○	
Column conditioned according to the manufacturer's recommendations	○	
In case of ion pairing separation, the column was additionally stabilized for >10h with running mobile phase before connecting the flow cell.	○	
In case of using an ISAAC reference: fixed concentration (... mmol/L) Cl <sup>-</sup> in mobile phase	○	

\* Any deviation observed must be documented in the 'non-conformance' record.

Verified by (customer): .....

Deviations (Y/N): .....

Comments:

## CHAPTER 5

## Operational familiarization

The ALEXYS LC-EC System has been designed for maximum functionality and ease of use. Most of the operational issues are intuitive, but a few issues require additional explanation.

Information regarding these issues is in the corresponding user manual.

**Table IV**

Check	In conf.	Non conf. ref. *
Concept of HPLC separation has been explained	<input type="radio"/>	
Concept of electrochemical detection has been explained	<input type="radio"/>	
Functional characteristics have been explained (if applicable) of: <ul style="list-style-type: none"> <li>- P6.1L pump</li> <li>- AS 110 autosampler</li> <li>- DECADE Elite electrochemical detector</li> <li>- Clarity data system software</li> </ul>	<input type="radio"/> <input type="radio"/> <input type="radio"/> <input type="radio"/>	
Application specific details have been explained - Analysis of ...	<input type="radio"/>	

\* Any deviation observed must be documented in the 'non-conformance' record.

Verified by (customer): .....

Deviations (Y/N): .....

Comments:

## CHAPTER 6

**Maintenance instructions**

The ALEXYS LC-EC System has been designed for maximum functionality and ease of use. Performing proper maintenance is key to prolonging the correct functioning of the system.

Receiving detailed information regarding maintenance is part of the training/instructions. For reference purpose, the instructions are also given in the corresponding user manuals of the instrument.

**Table V**

<b>Check</b>	<b>In conf.</b>	<b>Non conf. ref. *</b>
Daily maintenance routines were explained: - Autosampler needle wash - Check for leaks	<input type="radio"/> <input type="radio"/>	
Weekly maintenance routines were explained: - Refreshing the piston wash solution	<input type="radio"/>	
Half-yearly maintenance routines were explained: - Replacement of Whatman in-line filter	<input type="radio"/>	
Flow cell maintenance were explained: - Polishing of the working electrode - Polishing of the auxiliary electrode - Maintenance of the reference electrode	<input type="radio"/> <input type="radio"/> <input type="radio"/>	
Storage procedures were explained	<input type="radio"/>	
The use of a daily checklist** was explained	<input type="radio"/>	

\* Any deviation observed must be documented in the 'non-conformance' record.

\*\* See Appendix I

Verified by (customer): .....

Deviations (Y/N): .....

Comments:

## CHAPTER 7

## Troubleshooting instructions

Two tests are explained that an end-user should be able to do before contacting the manufacturer in case of detector related issues.

Detailed information is in the detector user manual.

**Table VI**

Check	In conf.	Non conf. ref. *
Troubleshooting tests were explained:		
- Dummy cell test	○	
- Stop flow test	○	

\* Any deviation observed must be documented in the 'non-conformance' record.

Verified by (customer): .....

Deviations (Y/N): .....

Comments:

C H A P T E R 8

# IQ certification

The installation has been performed in accordance to the Installation Qualification and has been carried out to the satisfaction of both parties. Designated operator has been trained and familiarized with the ALEXYS LC-EC System during the installation.

### Antec Scientific representative

Company: .....

Performer: .....

.....

Date Signature

### Customer (authorized to sign)

Company & Dept: .....

Reviewer/Customer: .....

.....

Date Signature

### Operator(s) trained for working with the ALEXYS system

Name: .....

Name:: .....

Name: .....

## CHAPTER 9

## Non-conformance record

Any case of non-conformance found during installation should be documented and signed for acceptance or corrective action taken.

**Table VII**


Ref.	Non-conformance and action taken	Signature customer	Sign. Antec Scientific rep.
1		.....	.....
2		.....	.....
3		.....	.....

## Comments

## A P P E N D I X I

## ALEXYS Operator Checklist

The newest digital version of our ALEXYS Operator Checklist can be downloaded from our website (document nr. 180\_0029).

		Date:			
<b>Mobile phase and waste</b>					
Enough mobile phase in the bottles					
Mobile phase not expired					
No microbial growth visible in the mobile phase bottle					
Waste bottle emptied					
Mobile phase replaced (at least every 3 days)					
<b>In-line Whatman filter</b>					
No air in the Whatman filter inlet					
No dots/stains/discoloration visible on membrane?					
Filter replaced (once/6 months)					
<b>Pump</b>					
Degasser lights green					
No air pockets in the inlet lines					
No wetness/salt build-up at the connectors of the degasser					
No wetness/salt build-up at the connectors of the pump head					
Piston wash level did not change					
Piston wash solution replaced (once/week)					
Piston seals replaced (once/year)					
<b>Auto sampler</b>					
Performed Initial wash					
No air on top of syringe or stuck in the buffer tubing					
Enough needle wash solution					
Check/empty the autosampler waste bottle					
No wetness/salts at valve connectors					
Needle wash solution replaced (at least once/week)					
Syringe tip replaced (once/year)					
<b>Flowcell</b>					
Crystals/no air visible (in an sb ref)					
Maintenance of reference - ISAAC or sb (at least once/3 months)					
<b>Before starting a complete sequence</b>					
Calibration file name cloned in method to match today's date					
Correct method 'Sent to instrument' and system is stabilizing					
Waste line lowered all the way into the Waste bottle					
Performed a system suitability test run and results are OK					
Any modifications to the integration table updated to the method					
Check marks applied to all sequence lines					
Bypass' mode set for lines used for stabilization or standby time					
<b>System values</b>					
Detector Ecell setting (mV)					
Detector I-cell reading					
Detector oven temperature (°C)					
Set vs. actual sample tray temperature (°C)					
Flow rate (µL/min)					
Pressure reading (bar)					
System suitability test run peak height					
System suitability test run plate count/m					
Baseline noise level estimation (visual peak-to-peak)					
Operator initials					
Remarks					